

# Notice of Allowability

Application No.

10/698,121

Examiner

Mahe M. Haddad

Applicant(s)

COSGROVE, DOMINIC

Art Unit

1644

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/30/07.
2. ☒ The allowed claim(s) is/are 6, 10, 11, 15, 21, 25, 45-52, 55-59, 62-66, and 98-73.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

### Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 10/26/07.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### DETAILED ACTION

1. Applicant's amendment, filed 8/30/07, is acknowledged.
2. Upon consideration the examiner has rejoined SEQ ID NO:2.

### EXAMINER'S AMENDMENT

3. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.
4. Authorization for this Examiner's Amendment was given in a telephone interview with Nancy A. Johnson on 10/26/07.

#### In the Claims:

5. Amend the claims as follows:

--1-5. (Canceled)

6. (Currently amended) The method of claim 59 or claim 66 wherein the antibody blocks the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on vascular endothelium of chronically inflamed tissues.

7-9. (Canceled)

10. (Currently amended) The method of claim 58 or claim 65 wherein the antibody is a monoclonal antibody.

11. (Currently amended) The method of claim 58 or claim 65 wherein the patient has renal fibrosis or crescentic glomerulonephritis.

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12-14. (Cancel)

15. (Currently amended) The method of claim 55 or claim 62 wherein the antibody blocks the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on the cell surface of the vascular/capillary endothelial cells of inflamed tissues.

16-20. (Canceled)

21. (Currently amended) The method of claim 56 or claim 63 wherein the antibody is a monoclonal antibody.

22-24. (Canceled)

25. (Currently amended) The method of claim 57 or claim 64 wherein the antibody is a monoclonal antibody.

26-44. (Canceled)

45. (Currently amended) The method of claim 55 or claim 62 wherein the antibody is a monoclonal antibody.

46. (Currently amended) The method of claim 56 or claim 63 wherein the antibody blocks the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on vascular endothelium of chronically inflamed tissues.

47. (Currently amended) The method of claim 57 or claim 64 wherein the antibody blocks the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on vascular endothelium of chronically inflamed tissues.

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48. (Currently amended) The method of claim 55 or claim 62 wherein the antibody inhibits binding of fluorochrome-conjugated purified  $\alpha 1\beta 1$  integrin to MCP-1 treated primary endothelial cells in culture.

49. (Currently amended) The method of claim 56 or claim 63 wherein the antibody inhibits binding of fluorochrome-conjugated purified  $\alpha 1\beta 1$  integrin to MCP-1 treated primary endothelial cells in culture.

50. (Currently amended) The method of claim 57 or claim 64 wherein the antibody inhibits binding of fluorochrome-conjugated purified  $\alpha 1\beta 1$  integrin to MCP-1 treated primary endothelial cells in culture.

51. (Currently amended) The method of claim 58 or claim 65 wherein the antibody inhibits binding of fluorochrome-conjugated purified  $\alpha 1\beta 1$  integrin to MCP-1 treated primary endothelial cells in culture.

52. (Currently amended) The method of claim 59 or claim 66 wherein the antibody inhibits binding of fluorochrome-conjugated purified  $\alpha 1\beta 1$  integrin to MCP-1 treated primary endothelial cells in culture.

53-54. (Canceled)

55. (Currently Amended) A method of reducing selective efflux of integrin  $\alpha 1\beta 1$ -positive monocytes into the interstitium of chronically inflamed tissues, the method comprising contacting the  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with an antibody to Collagen XIII that interferes with the interaction between Collagen XIII and  $\alpha 1\beta 1$  integrin, wherein the antibody binds to a ~~peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:1~~ polypeptide, said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having SEQ ID NO:1.

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56. (Currently Amended) A method of reducing the rate of monocyte efflux into the interstitial space of chronically inflamed tissues, the method comprising contacting the tissue with an antibody to Collagen XIII, wherein the antibody blocks Collagen XIII from binding with  $\alpha 1\beta 1$  integrin, and wherein the antibody binds to a ~~peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:1~~ polypeptide, said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having SEQ ID NO:1.

57. (Currently Amended) A method of blocking the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on vascular endothelium of chronically inflamed tissues, the method comprising contacting the monocytes, the vascular endothelium, or both with an antibody to Collagen XIII, wherein the antibody binds to a ~~peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:1~~ polypeptide, said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having SEQ ID NO:1.

58. (Currently Amended) A method of treating a patient having chronically inflamed kidneys associated with an accumulation of  $\alpha 1\beta 1$  integrin positive monocytes in the interstitium, the method comprising administering to the patient an antibody to Collagen XIII, wherein the antibody reduces the rate of efflux of  $\alpha 1\beta 1$  integrin positive monocytes into the renal interstitium, and wherein the antibody binds to a ~~peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:1~~ polypeptide, said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having SEQ ID NO:1.

59. (Currently Amended) A method of treating a patient having renal fibrosis, the method comprising administering to the patient an antibody to Collagen XIII, wherein the antibody prevents the binding of Collagen XIII to  $\alpha 1\beta 1$  integrin positive monocytes, and wherein the antibody binds to a ~~peptide fragment of Collagen XIII, the peptide fragment having SEQ ID~~

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NO:1 polypeptide, said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having SEQ ID NO:1.

60-61. (Canceled)

62. (Currently amended) [[The]] A method of reducing selective efflux of integrin  $\alpha 1\beta 1$ -positive monocytes into the interstitium of chronically inflamed tissues, the method comprising contacting the  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with an antibody to Collagen XIII that interferes with the interaction between Collagen XIII and  $\alpha 1\beta 1$  integrin, ~~claim 55~~ wherein the antibody binds to a peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:2 polypeptide, said polypeptide consisting of SEQ ID NO:2 or said polypeptide consisting of SEQ ID NO:2 with a deletion of one amino acid residue from one or both termini.

63. (Currently Amended) [[The]] A method of reducing the rate of monocyte efflux into the interstitial space of chronically inflamed tissues, the method comprising contacting the tissue with an antibody to Collagen XIII, wherein the antibody blocks Collagen XIII from binding with  $\alpha 1\beta 1$  integrin and, ~~claim 56~~ wherein the antibody binds to a peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:2 polypeptide, said polypeptide consisting of SEQ ID NO:2 or said polypeptide consisting of SEQ ID NO:2 with a deletion of one amino acid residue from one or both termini.

64. (Currently Amended) [[The]] A method of blocking the interaction of  $\alpha 1\beta 1$  integrin on peripheral blood monocytes with Collagen XIII on vascular endothelium of chronically inflamed tissues, the method comprising contacting the monocytes, the vascular endothelium, or both with an antibody to Collagen XIII, ~~claim 57~~ wherein the antibody binds to a peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:2 polypeptide, said polypeptide consisting of SEQ ID NO:2 or said polypeptide consisting of SEQ ID NO:2 with a deletion of one amino acid residue from one or both termini.

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65. (Currently Amended) [[The]] A method of treating a patient having chronically inflamed kidneys associated with an accumulation of  $\alpha 1\beta 1$  integrin positive monocytes in the interstitium, the method comprising administering to the patient an antibody to Collagen XIII, wherein the antibody reduces the rate of efflux of  $\alpha 1\beta 1$  integrin positive monocytes into the renal interstitium, and ~~claim 58~~ wherein the antibody binds to a peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:2 polypeptide, said polypeptide consisting of SEQ ID NO:2 or said polypeptide consisting of SEQ ID NO:2 with a deletion of one amino acid residue from one or both termini.

66. (Currently Amended) [[The]] A method of treating a patient having renal fibrosis, the method comprising administering to the patient an antibody to Collagen XIII, wherein the antibody prevents the binding of Collagen XIII to  $\alpha 1\beta 1$  integrin positive monocytes, and ~~claim 59~~ wherein the antibody binds to a peptide fragment of Collagen XIII, the peptide fragment having SEQ ID NO:2 polypeptide, said polypeptide consisting of SEQ ID NO:2 or said polypeptide consisting of SEQ ID NO:2 with a deletion of one amino acid residue from one or both termini.

67. (Cancelled)

68. (Currently amended) The method of claim 55 or claim 62 wherein the antibody reduces the rate of efflux of  $\alpha 1\beta 1$  integrin positive monocytes into the interstitial space at the site of inflammation.

69. (Currently amended) The method of claim 56 or claim 63 wherein the antibody reduces the rate of efflux of  $\alpha 1\beta 1$  integrin positive monocytes into the interstitial space at the site of inflammation.

70. (Currently amended) The method of claim 57 or claim 64 wherein the antibody reduces the rate of efflux of  $\alpha 1\beta 1$  integrin positive monocytes into the interstitial space at the site of inflammation.

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71. (Currently amended) The method of claim 59 or claim 66 wherein the antibody reduces the rate of efflux of  $\alpha 1 \beta 1$  integrin positive monocytes into the interstitial space at the site of inflammation.

72. (Currently amended) The method of claim 59 or claim 66 wherein the antibody is a monoclonal antibody.

73. (Currently amended) The method of any one of claim 55, 56, 57, 58, or 59, wherein the antibody binds to a polypeptide, ~~said polypeptide consisting of a peptide fragment of Collagen XIII, said polypeptide consisting of 8 to 16 amino acid residues, and said polypeptide having~~ SEQ ID NO:1.

74. (Canceled)--

6. Claims 6, 10, 11, 15, 21, 25, 45-52, 55-59, 62-66, and 98-73 are allowed.

#. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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